K132842
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510(k) Summary

FEB 21 2014

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2. Contact Person	Name: Choul-Woo Shin Position: Vice President E-mail: cwshin@drtech.co.kr Telephone: + 82-31-784-8856
3. Date Prepared	August 16, 2013
4. Device Classification Name	Stationary x-ray system
5. Device Name	Digital X-Ray Detector FLAATZ 600 Series (FLAATZ 600/601)
6. Reason for Submission	New Device
7. Classification	21 CFR 892.1680
8. Product Code	MQB
9. Predicate Device	FLAATZ 560 DRTECH Corporation 510(k) No. K111583

10. Device Description

The FLAATZ 600 Series (FLAATZ 600/601) is a radiographic image acquisition device. It is a fully integrated image capture and routing system under human operator control. This system may be usable by a technician in a typical radiology environment.

The FLAATZ 600 Series (FLAATZ 600/601) system includes a Detector Panel, Case, Grid, Power Box, Switch Box, Interconnecting Cables, and API. The Detector Panel is a direct conversion device in the form of a rectangular plate in which the input x-ray photons are absorbed in an a-Se layer. The Power Box functions as a buffer between the Detector

Panel and Operating PC while also supplying power to the Detector Panel. The Switch Box transfers signals between the Power Box and X-ray Generator and also indicates the status of the panel using LED lights. .Finally, the API contains functions for image data capture and correction of defects on the image data.

11. Intended Use

The FLAATZ 600 Series (FLAATZ 600/601) is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications).

12. Summary of the Technological Characteristics to the Predicate Device

The modification to the predicate device is the change of data communication methods as Ethernet & Wireless type. There are no changes to the product performance specifications, device indications for use/intended use.

13. Summary of Non-Clinical Testing

The performance of Detector can be evaluated by DQE and MTF according to IEC 62220-1:2003 Standard.DQE & MTF have been tested by acquiring the X-ray image with designated devices. Moreover, FLAATZ 600 Series is in accordance with Safety, EMC and DICOM standards (IEC 606001-1:2005, IEC 60601-1- 2:2007 and NEMA PS 3.1-3.20:2011) The test results conclude that FLAATZ 600 Series (FLAATZ 600/601) is substantially equivalent compared to the predicate device (FLAATZ 560)

14. Summary of Clinical Testing

Clinical study is to investigate the diagnostic equivalency of detector panels with the same a-Se technology and same pixel sizes. We've tested for eight body parts (Chest, Shoulder, L-Spine_L, L-Spine_AP, Hand, Forearm, Foot and Knee) compared to the predicate device. The result of tests, FLAATZ 600 Series (FLAATZ 600/601) produces diagnostic images of equivalent quality as the predicate device (FLAATZ 560)

15. Substantial Equivalence

The proposed FLAATZ 600 Series (FLAATZ 600/601) has identical indication for use / intended use, the principal of operation and user environment.
The proposed FLAATZ 600 Series (FLAATZ 600/601) has similar performance in terms of DQE, MTF and is the same physical characteristics as using Amorphous Selenium (a-Se) material. Moreover, FLAATZ Series (FLAATZ 600/601) is the upgraded model of its

previous model FLAATZ 560. TFT panel and main components are almost same.

16. Functional and Safety Testing

The FLAATZ 600 Series (FLAATZ 600/601) has been evaluated as per FDA's "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices" and has shown good performance, substantially equivalent to the predicate device.

The FLAATZ 600 Series (FLAATZ 600/601) has also met applicable Electro Magnetic Compatibility (EMC) requirements.

17. Conclusion

The FLAATZ 600 Series (FLAATZ 600/601) is substantially equivalent to the Predicate Device in design and performance.

18. Manufacturing Facility

DRTECH Corporation
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

DRTECH Corporation
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SOUTH KOREA

Re: K132842
Trade/Device Name: FLAATZ 600 Series (FLAATZ 600/601)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 13, 2014
Received: January 24, 2014

Dear Choul-Woo Shin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132842

Device Name
FLAATZ 600 Series (FLAATZ 600/601)

Indications for Use *(Describe)*
The FLAATZ 600 Series (FLAATZ 600/601) is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*